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(71) Applicant: CROWN LABORATORIES, INC. [US/US]; 6780 Caballo Street, Las Vegas, NV 89119 (US).

(72) Inventors: NASH, Scott, Oldham; 678 Cervantes Drive, Henderson, NV 89014 (US). NASH, Craig, Emery; Apartment 234, 230 E. Flamingo Road, Las Vegas, NV 89109 (US). PARK, Peter, S., W.; 1985 Waverly Circle, Henderson, NV 89014 (US).

(74) Agent: WALDBAUM, Maxim, H.; Fried, Frank, Harris, Shriver & Jacobson, One New York Plaza, New York, NY 10004 (US).

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(54) Title: IMPROVED LIQUID NUTRITIONAL SUPPLEMENT AND ASEPTIC PROCESS FOR MAKING SAME

(57) Abstract

An improved nutritional supplement and aseptic process for making same is provided. The liquid nutritional supplement provides improved concentration of many recommended both macro– and micro–nutrients in a shelf–stable form. A process for making the improved nutritional supplement is also provided, in which the supplement is subjected to higher–pressure homogenization of the supplement after ultra–high temperature turbulent flow sterilization. The improved nutritional supplement of the present invention provides a higher level of nutrients with many recommended minerals and vitamins in a smaller volume than supplements not having the high level of total solids of the liquid nutritional supplement of the present invention. The supplement also has an improved mouth feel, flavor profile and taste, resulting in higher intake of the supplement, especially beneficial for effective nutritional management of consumers with comprised stomach capacity.

Sterile Prod
w/ oil.

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IMPROVED LIQUID NUTRITIONAL SUPPLEMENT AND ASEPTIC PROCESS FOR MAKING SAME

Background Of The Invention

The present invention is directed to an improved nutritional supplement and process for making same, and more particularly, to a liquid nutritional supplement which provides improved concentration of many recommended macro- and micro-nutrients in a shelf-stable form. The present invention is also directed to a process for improving the shelf-stability and flavor profile of a liquid nutritional supplement, in which the supplement undergoes ultra-high temperature (UHT) processing while flowing through the UHT processor in a turbulent state and is then subjected to higher-pressure homogenization.

Currently, there are several liquid nutritional supplements available on the market, which have found application in many areas, including as a meal supplement or a meal replacement. The supplements contain enhanced levels of protein, fat, carbohydrate, vitamins and minerals which may benefit the consumers of the supplements in accomplishing balanced nutrition and thus maintain a good health. They are flavored and homogenized to improve their appearance, flavor profiles and taste, which are important factors in consumer acceptability and commercial success of the supplement. Supplements of this type include ENSURE and PULMOCARE brands from Ross Laboratories, a division of Abbott Laboratories, SUSTACAL and TRAUMACAL brands from Mead Johnson & Co., and RESOURCE from Sandoz Ltd. These supplements generally have a total solids content under 30% by total weight of the supplement, and thus have an large excess of water as compared to the amount of water necessary to solubilize the components of the supplement.

Nutritional supplements on the market today are available in no less than 8 or 10 ounce sizes, and in order to obtain the full benefit of the dietary supplement it must be entirely consumed. However, as a result of age-related and other factors, some people often have an undersized stomach and reduced appetite, so that the total volume of liquid and solid food which can be consumed is limited. An example of a patent directed to a higher-volume dietary supplement is U.S. Patent No. 4,497,800 to Larsen et al.

In addition, the presence of high levels of nutrients, especially minerals, while essential to the effectiveness of a nutritional supplement, has a counterproductive effect on the solubility of the components of the supplement and the consistency of the resulting liquid. In particular, the components can separate out into organic and aqueous phases, and minerals

can settle out of the liquid to form sedimentation on the bottom of the container during the expected shelf life of the packaged supplement. Such separation and sedimentation are undesirable for a number of reasons. One, it is visually unappealing to intended consumers of the supplement, and reduces the likelihood that the supplement will be fully consumed. Second, it reduces the efficacy of the supplement, if the minerals have settled out of the liquid being consumed and hardened into a nondispersible form.

The liquid nutritional supplement must also be sterilized so that it will be "commercially sterile," or safe for human consumption during its expected shelf life. Conventionally, liquid nutritional supplements have been sterilized through the use of a post-packaging retorting process, in which a homogenized liquid mixture of nutrients is packaged in a hermetically sealed container and then the container is subjected to steam heating under pressure for an extended period of time equivalent to approximately 5-10 minutes at 121 °C. From the onset of steam-on to steam-off, this process could take 20-60 minutes to accomplish commercial sterility. This retorting process is abusive to the container itself as well as the heat-sensitive nutrients of liquid nutritional supplements, and may accelerate the process of separation and sedimentation discussed above. It also exerts an adverse effect on the aroma and taste of the final product. U.S. Patent No. 4,497,800 to Larsen et al. is one example of a supplement sterilized by this retorting process.

Another method for sterilizing certain types of nutritional formulations is referred to as continuous thermal or UHT (ultra-high temperature) processing, also known as aseptic processing. UHT processing can be accomplished by direct injection of steam into the liquid to be sterilized, or by indirect heating of the liquid as it flows through a tube surrounded by steam or past a heat exchanger plate. The raw product is sterilized before being packaged in previously sterilized containers. In this aseptic process, the product mixture is subjected to brief but intense heating in the temperature range of 130-145 °C, for a time sufficient to commercially sterilize the product, approximately 2-45 seconds. The use of UHT processing to sterilize a certain kind of nutritional formulation having a high acidity and primarily using whey as the protein component of the nutritional supplement is discussed in U.S. Patent No. 5,520,948 to Kvamme. The use of UHT processing in the preparation of a liquid nutritional supplement requiring the use of high proportion of a certain kind of stabilizer, iota-carrageenan, to maintain shelf stability is taught in U.S. Patent No. 5,416,077 to Hwang et al.

The use of UHT processing is also known in the preparation of infant formula, dairy products, and non-dairy creamers, which all have much lower levels of nutrients than the nutritional supplements. Examples include U.S. Patent No. 4,748,028 to McKenna et al; U.S.

Patent No. 4,851,243, U.S. Patent No. 4,888,194, and U.S. Patent No. 4,9335,255, all to Anderson et al.; and U.S. Patent No. 5,378,488 to Dimler et al.

The use of UHT processing in conventional low-acid liquid nutritional supplements using milk proteins such as caseinates as their protein source has encountered a number of difficulties. These difficulties are caused in part by the localized build-up of heat within the supplement during UHT processing. They are also caused in part by the high levels of micro-nutrient minerals present in the supplement, combined with the high levels of sources of protein and fat macro-nutrients. These difficulties include nonenzymatic browning, or "burn on", which causes an undesirable color and unpleasant flavor. In addition, fouling of the processing tubing has been encountered, caused by sedimentation and separation of the components during UHT sterilization. In an attempt to reduce the likelihood that minerals will separate out of the supplement during ultra high temperature processing, prior art supplements sterilized using this technique use if possible water-soluble compounds as sources of minerals. For example, ferrous sulfate is used as a source of iron.

As a result of the presence of both hydrophobic and hydrophilic components in the liquid nutritional supplement, they are conventionally subjected to homogenization during processing. This improves the shelf stability as well as the flavor profile and appearance of the final liquid nutritional supplement. However, this homogenization is usually performed prior to UHT sterilization at pressures not exceeding 2,500 pounds per square inch (psi), based on experience gained in homogenization of dairy products.

In light of the above, it would be desirable to provide a liquid nutritional supplement which provides improved concentration of many recommended macro- and micro-nutrients in a shelf-stable form. It would also be desirable to provide a fully aseptic sterilization and homogenization process for a liquid nutritional supplement resulting in improved shelf-stability and flavor profile.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided an improved liquid nutritional supplement which provides improved concentration of many recommended nutrients in a shelf-stable form. As used herein, a liquid nutritional product is "shelf-stable" if it is essentially devoid of separation or sedimentation over the expected shelf life of the product.

The liquid nutritional supplement comprises:

(a) a macro-nutrient component comprising 22 to 150 milligrams of protein and 30 to 200 milligrams of fat per milliliter of supplement; and

(b) a mineral micro-nutrient component comprising 1.5 to 10 milligrams of potassium; 0.4 to 2.97 milligrams of calcium; 0.17 to 1.18 milligrams of magnesium; 0.42 to 2.97 milligrams of phosphorus; and 0.015 to 0.053 milligrams of iron per milliliter of supplement;

wherein the nutritional supplement is commercially sterile and shelf-stable.

In another aspect of the present invention, the commercially sterile and shelf-stable liquid nutritional supplement comprises:

(a) a macro-nutrient component comprising at least one source of protein, at least one source of fat, and at least one source of carbohydrate,

(b) a mineral micro-nutrient component comprising at least one source of mineral micro-nutrients which is virtually water-insoluble, and

(c) a stabilizer,

wherein the total solids present in the supplement is not less than 30% of the total weight of the supplement.

In an additional aspect of the invention, the liquid nutritional supplement is sterilized by continuous thermal processing at ultra-high temperature and comprises as a source of iron ferric ortho-phosphate.

One aspect of the invention is a process for maintaining emulsion stability and extending the shelf life of a liquid nutritional supplement formulated as an emulsified slurry comprising sources of macro-nutrients and then sterilized, comprising the step of passing the emulsified slurry through a pump exerting a hydroshear of between 100 to 250 pounds per square inch.

In another aspect of the present invention, a process for aseptically sterilizing and homogenizing a liquid nutritional supplement comprises the steps of:

(a) heating the supplement to a temperature of at least 130 °C for a time sufficient to commercially sterilize the supplement while the supplement is passing through a hold tube under a pressure sufficient to keep the flow of the supplement through the hold tube substantially turbulent;

(b) passing the supplement through a remote aseptic homogenizer having at least one valve creating a pressure of at least 2,800 pounds per square inch

wherein the valve also acts as a pressure restrictor on the supplement flow out of the hold tube.

Yet another aspect of the invention is, in a processor for commercially sterilizing a liquid having an entry point and an exit point for the liquid, a hold tube between the entry and exit points, a chamber holding steam adjacent the hold tube for indirectly heating the liquid in the hold tube to a temperature of at least 130 °C for a time sufficient to commercially sterilize the supplement while the supplement is passing through the hold tube, and a means for restricting the flow of the liquid out of the processor, the improvement which comprises:

(a) increasing the thickness of the walls of the hold tube so that the hold tube can withstand pressures up to 4,000 pounds per square inch;

(b) creating a continuous positive pressure through the system by the use of at least one positive displacement pump controlled by a variable speed drive; and

(c) dynamically controlling the pump, the processor, and the means for restricting the flow of the liquid out of the processor to ensure that the pressure remains sufficiently high to keep the flow of the liquid through the hold tube substantially turbulent.

A further aspect of the invention is, in a processor for commercially sterilizing a liquid having a hold tube between the entry and exit points, and a chamber holding steam adjacent the hold tube for indirectly heating the liquid in the hold tube to a temperature of at least 130 °C for a time sufficient to commercially sterilize the supplement while the supplement is passing through the hold tube, the improvement which comprises:

maintaining a pressure on the liquid through the hold tube which is higher than the pressure on the steam in the chamber adjacent the hold tube, such that if a leak in the hold tube develops, no steam will enter the hold tube and contaminate the sterile liquid in the hold tube.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is concerned with the formulation and manufacture of an improved, commercially sterile liquid nutritional supplement. Thus, the description which follows should be considered illustrative of a preferred embodiment and best mode for practicing the invention, and not in any way a limit on the scope or applicability of the various aspects of the invention herein.

In a preferred embodiment, the process for aseptically preparing and packaging the improved liquid nutritional supplement of the present invention comprises (A) blending and

liquefying of ingredients to form an emulsion and (B) higher pressure sterilization by continuous thermal processing at ultra-high temperature followed by higher-pressure homogenization. The apparatus used to perform the various mechanical steps is any suitable equipment well-known to one skilled in the art, unless otherwise stated. This preferred process is discussed below.

A. Blending and Liquefying of Ingredients

One or more sources of proteins and one or more sources of carbohydrate are blended into a dry macro-nutrient mixture. Optionally, a stabilizer such as kappa-carrageenan and a wetting agent such as polysorbate 60 or 80 may be used. In a most preferred process, the protein is calcium sodium caseinates, and the carbohydrate is a fine sugar, which are used together with a stabilizer and a wetting agent in amounts as described below in Examples A and B. An alternative protein source is milk protein concentrate which has been subjected to ultrafiltration to reduce lactose. In a first mixing tank, this dry macro-nutrient mixture is then added to heated water and hydrated or solubilized into an aqueous formulation slurry.

Sources of minerals including potassium, calcium, magnesium, phosphorous and iron are blended into a dry mineral micro-nutrient mixture, and then mixed in water to form a mineral micro-nutrient slurry. This mineral micro-nutrient slurry is added to the aqueous formulation slurry. Most preferred sources and amounts of these minerals are described below in connection with Examples A and B.

Sources of trace minerals including iron, zinc, copper and iodine are blended into a dry trace mineral micro-nutrient mixture, and then mixed in water to form a trace mineral micro-nutrient slurry. A proper amount of the trace mineral micro-nutrient slurry is then added to the aqueous formulation slurry. Most preferred sources and amounts of these trace minerals are described below in connection with Examples A and B.

The pH of the nutrient slurry is then adjusted to about 6.9 to 7.0, or about 7.0 to 7.2 if an optional additional source of carbohydrate is added as discussed below. A source of fat is then added with agitation to form an emulsion with the aqueous nutrient slurry. The source of fat is most preferably one high in monounsaturated fatty acids, such as high oleic safflower oil, used in amounts as described below in connection with Examples A and B. Optionally, lecithin and vitamin E acetate can be added at this point to improve the emulsification and nutritional qualities of the supplement.

At this point, optionally an additional source of carbohydrate such as maltodextrin can be added to the emulsified slurry. Butter flavor, a vitamin premix of the type well known in the liquid nutritional supplement industry (such as those commercially available from Hoffman LaRoche, Inc., of Nutley, New Jersey, for example), sodium ascorbate and if desired chocolate flavor can be added to the emulsified slurry. The flavoring agents used herein may be any of a number of flavoring agents well known in the nutritional supplement industry (such as those commercially available from Universal Flavors, of Indianapolis, Indiana, for example). After agitation, the total solids of the emulsified slurry are adjusted by addition of water to not less than 30% of the total weight of the emulsified slurry. In the alternative embodiment including the addition of maltodextrin, the total solids are adjusted to not less than 38% of the total weight. Most preferred amounts of these ingredients are stated below in connection with Examples A and B.

The solids-adjusted emulsified slurry is then passed through a tubular heat exchanger to a second mixing tank, passing through a pump exerting a hydroshear on the slurry of from between 100 to 250 psi. Alternatively, a homogenizer may be used in place of the hydroshear pump. However, without wishing to be bound by theory, it is believed that the use of a pump to hydroshear the emulsified slurry makes a more effective contribution than a homogenizer to the maintenance of an emulsion during overnight storage and deaeration. It is also believed that the use of a pump exerting a hydroshear to "deface" the supplement suspension may extend the shelf life and control gellation in the final liquid nutritional supplement product. In addition, a pump containing a hydroshear is easier to maintain and clean when necessary than a standard homogenizer.

The slurry is then cooled and optionally flavored vanilla or strawberry to form the final supplement mixture. In addition, the cooled supplement mixture may be refrigerated at or below 7 °C and allowed to stand overnight (or at least 6 hours), which allows the supplement mixture to deaerate. Without wishing to be bound by theory, it is believed that this process of passing the emulsified slurry through a pump exerting a hydroshear and then allowing the supplement mixture to stand overnight results in a supplement with extended shelf life. Most preferred amounts of these ingredients and conditions of hydroshear and storage are stated below in connection with Examples A and B.

The resulting nutritional supplement mixture is high in macro- and micro-nutrients, and provides about 1.7 calories per milliliter (cal/ml). If the optional additional source of carbohydrate is added, the supplement mixture provides about 2.0 cal/ml. Moreover, it is

much lower in sodium than liquid nutritional supplements not made according to the present invention, as illustrated below in the Comparative Nutrient Values chart.

B. Higher Pressure Sterilization and Homogenization

The cooled final supplement mixture is subjected to continuous thermal processing at ultra-high temperature (i.e., at a temperature of at least 130 °C) for a time sufficient to commercially sterilize the supplement while the supplement is passing through a hold tube under sufficient pressure to keep the flow of the supplement through the hold tube substantially turbulent. To achieve the sterilization required by applicable Food and Drug Administration regulations, the supplement mixture is exposed to temperature of about 140 to 145 °C in the hold tube for about 2 to 45 seconds. In a most preferred process, the supplement is heated indirectly by steam while flowing through a spiral hold tube, the sterilization temperature is about 142 to 144 °C, and the total time in the hold tube at sterilization temperatures is 3 to 6 seconds. Alternatively, a straight or trombone-style tubing system can be employed. As exposure to sterilization temperature causes some destruction of the vitamins within the supplement mixture, the amount of vitamins added during formulation can be adjusted for longer or shorter sterilization times so as to result in the proper amount of vitamins in the final liquid nutritional supplement.

The UHT processing is performed using a Stork Sterideal Model 8000B indirect continuous thermal processor which has been specially modified to generate and then to withstand the pressure necessary to keep the flow through the processor substantially turbulent. First, the processor has been modified by use of high-pressure tubing having walls between 4.5 and 6 millimeters thick, and capable of withstanding pressures up to 4,000 psi. Second, the Stork processor has also been modified to provide for continuous positive pressure through the system by the use of one or more pumps having a variable speed drive and positive displacement to push the supplement into the UHT processor. Third, these pumps are dynamically controlled together with the modified Stork processor and a means for controlling the flow of the supplement out of the processor (most preferably the higher-pressure remote aseptic homogenizing valves (described below)) by the use of a computer to ensure that the pressure remains sufficiently high to keep the flow of the supplement through the hold tube substantially turbulent. In a most preferred process, the flow level is between 2,000 and 8,000 liters per hour. By the use of these modifications, the pressure within the hold tube of the modified processor is not less than 2,800 psi, and the pressure drop through the modified processor in the most preferred process is not greater than 500 psi. The unmodified Stork Model 8000B is available from Stork Amsterdam of Amstelveen, Netherlands.

The flow of the supplement through the tubing is considered "turbulent", as used herein, if it contains at least some internal flow patterns in directions non-parallel to the direction of flow of the supplement through the tubing. It is believed that this turbulent flow prevents the localized build-up of heat and allows the sterilization heat to disperse more evenly and rapidly throughout the supplement in the tube than non-turbulent, laminar flow. Thus, it is believed that the turbulent flow of the supplement during UHT processing contributes to the improved flavor profile and taste of the sterilized nutritional supplement, and also prevents heat-induced emulsion instability which could lead to fouling of the UHT processing system and shorten the expected shelf life of the packaged supplement.

The supplement is then subjected to a remote (i.e., after sterilization) aseptic homogenizing valve creating a pressure of at least about 2,800 psi. Optionally, the supplement is then passed through a second homogenizing valve creating a pressure of about 500 to 1,000 psi. In a most preferred process, the supplement is subjected to double-stage "downstream" (i.e., after sterilization) homogenization at a first stage valve pressure of approximately 3,100 psi, and a second stage valve pressure of about 500 psi. The first stage homogenization valve also acts as a pressure restrictor on the supplement flow out of the tubing of the modified Stork UHT processor, thereby (1) keeping the pressure within the hold tube sufficiently high so that the flow of the supplement is substantially turbulent and (2) eliminating the need for a separate "stuffer" pump to feed the supplement through the homogenizing valves. Without being bound by theory, it is believed that pressures above about 2,800 psi are more effective at homogenizing vegetable oils such as safflower oil, which are the sources of fat used in nutritional supplements, than conventional pressures of around 2,500 psi currently used in the nutritional supplement industry, which were designed based on experiences with dairy products having milk fats.

As part of this higher pressure UHT processing, the supplement in the hold tube is at a higher pressure than the steam in a chamber adjacent the hold tube used to indirectly heat the supplement flowing through the hold tube to the sterilization temperature. Thus, if a small leak in the tubing develops, no steam will enter the hold tube and contaminate the sterile liquid in the hold tube. A small amount of supplement may escape into the adjacent steam, but this will not affect the sterility of the supplement remaining in the hold tube and exiting the processor. Moreover, because the pressure on the supplement increases as the supplement passes through the hold tube, the sterile supplement toward the end of the hold tube is at a higher pressure than the supplement which has just entered the processor. Upon entering the processor, this non-sterile supplement may pass through tubing adjacent to the tubing holding

the outgoing sterile supplement in order to receive heat from the outgoing sterile supplement. Thus, if a small leak develops in the tubing between the entering non-sterile supplement and the exiting sterile supplement, the sterile supplement will not be contaminated by non-sterile supplement. This ensures that the supplement remaining in the tube and exiting the processor will be sterile, in compliance with applicable U.S. Food and Drug Administration requirements, and thus will not need to be discarded.

As a result of this higher-pressure homogenization, the product is thoroughly homogenized, resulting in reduction of droplet size as compared to liquid nutritional supplements homogenized at lower pressures. The higher-pressure sterilization and homogenization of the present invention leads to prolonged emulsion stability and expected shelf life, and to a liquid product having superior mouth feel and flavor.

The following examples provide illustration of the invention but are not intended to limit the scope of the invention hereto. Examples A and B are liquid nutritional supplements formulated in accordance with most preferred embodiments of the instant invention. To illustrate the improvement represented by the present invention, following Examples A and B is a chart comparing the macro- and mineral micro-nutrient values of four ounces (118 ml) of Example A with four ounces of two prior art supplements, TRAUMACAL available from Mead Johnson & Co., and PULMOCARE available from Ross Laboratories, a division of Abbot Laboratories, Inc.

Example A

To form the dry macro-nutrient mixture, 805 pounds (lbs) of calcium sodium caseinate, 800 lbs of fine sugar, 2.6 lbs of polysorbate 80 and .84 lbs of kappa-carrageenan are blended together. This dry macro-nutrient mixture is then added to 5,500 lbs of water which has been pretreated through reverse osmosis and deonization, and heated to about 43 to 54 °C. This aqueous formulation slurry is then blended for 15 minutes.

To form the dry mineral micro-nutrient mixture, 32 lbs of dipotassium phosphate, 28 lbs of potassium citrate, 34 lbs of magnesium chloride, 5 lbs of magnesium carbonate, 5 lbs of calcium phosphate (tribasic) and 6 lbs of calcium carbonate are added to 30 gallons of pretreated water to form the mineral micro-nutrient slurry. The entire volume of this mineral micro-nutrient slurry is then added to the aqueous formulation slurry.

The inventors have found the use of magnesium carbonate as a source of magnesium to be particularly advantageous in the relatively concentrated liquid nutritional supplement of

the present invention, which has total solids of not less than 30% of the total weight of the supplement. This is because, as a virtually water-insoluble compound, magnesium carbonate does not tax the limited water available in the supplement. The inventors have found that the magnesium carbonate can be kept in suspension over the expected shelf life of the product by the use of a stabilizer, most preferably kappa-carrageenan. For the same reasons, the inventors have found the use of calcium carbonate, another virtually water-insoluble source of a mineral micro-nutrient, to be particularly advantageous. This source of calcium can also be kept in suspension by the use of a stabilizer which is most preferably kappa-carrageenan.

To form the dry trace mineral micro-nutrient mixture, 544 grams (g) of ferric ortho-phosphate, 454 g of zinc sulfate, 95 g of copper gluconate and 1.4 g of potassium iodide are added to 1 gallon of pretreated water to form the trace mineral micro-nutrient slurry. The entire volume of this trace mineral micro-nutrient slurry is then added to the aqueous formulation slurry. The aqueous formulation slurry is then agitated and maintained at about 43 to 54 °C to solubilize and fully hydrate, or to suspend, the macro- and micro-nutrients in the slurry.

The inventors have found the use of ferric ortho-phosphate as a source of iron to be particularly advantageous for two reasons. One, it is virtually water-insoluble, and so does not tax the limited water available in the relatively concentrated liquid nutritional supplement of the present invention, as explained above. The inventors have found that it can be kept in suspension by the use of a stabilizer, most preferably kappa-carrageenan. Two, it does not cause discoloration of the liquid nutritional supplement during continuous thermal processing at ultra-high temperatures. The inventors have determined that the use of ferrous sulfate, which is commonly used in liquid nutritional supplements as a source of iron, causes the liquid nutritional supplement to turn gray during UHT processing. This discoloration makes the liquid nutritional supplement less appealing to the intended consumer and may require the use of strong colorings in order to mask the discoloration. Without wishing to be bound by theory, it is believed that the formation of iron sulfide during UHT processing causes this discoloration.

Following the blending of the aqueous formulation slurry for 5 minutes, the pH is adjusted to 6.9 to 7.0 with 20% potassium hydroxide. Then 830 lbs of high oleic safflower oil, preheated to 93 °C are added to the aqueous formulation slurry. Vitamin E acetate in the amount of 0.6 lbs and lecithin in the amount of 32 lbs are dissolved in 50 lbs of safflower oil and added to the aqueous formulation slurry. The mixture is then agitated to further the emulsification and blending process for about 15 minutes. Butter flavor (2.5 lbs), and a

vitamin dry mixture of 4.6 lbs of vitamin premix and 3.2 lbs of sodium ascorbate are added to the emulsified slurry. The emulsified slurry is then blended for 5 minutes and the total solids are adjusted to 31.5 % of the total weight of the emulsified slurry.

The emulsified slurry is then passed through a Moyno type pump exerting a hydroshear between 195 to 205 psi at 150 gallons per minute and then cooled to about 22 °C. The cooled slurry is then flavored with 23 lbs of vanilla flavoring to form the final supplement mixture. The cooled supplement mixture is then refrigerated at 2-4 °C and allowed to stand overnight before being subjected to UHT sterilization and aseptically packaged.

Example B

To form the dry macro-nutrient mixture, 480 pounds (lbs) of calcium/sodium caseinate, 550 lbs of fine sugar, 2.6 lbs of polysorbate 60 and 1.70 lbs of kappa-carrageenan are blended together. This dry macro-nutrient mixture is then added to 4,400 lbs of water which has been pretreated through reverse osmosis and deonization, and heated to about 43 to 54 °C. This aqueous formation slurry is then blended for 15 minutes.

To form the dry mineral micro-nutrient mixture, 15 lbs of dipotassium phosphate, 50 lbs of potassium citrate, 23 lbs of magnesium chloride, 1.0 lbs of calcium phosphate (tribasic) and 20 lbs of calcium carbonate are added to 30 gallons of pretreated water to form the mineral micro-nutrient slurry. The entire volume of this mineral micro-nutrient slurry is then added to the aqueous formulation slurry.

To form the dry trace mineral micro-nutrient mixture, 272 grams (g) of ferric ortho-phosphate, 227 g of zinc sulfate, 50 g of copper gluconate and 0.68 g of potassium iodide are added to 1 gallon of pretreated water to form the trace mineral micro-nutrient slurry. The entire volume of this trace mineral micro-nutrient slurry is then added to the aqueous formulation slurry. The aqueous formulation slurry is then agitated and maintained at about 43 to 54 °C to solubilize and fully hydrate, or to suspend, the macro- and micro-nutrients in the slurry.

Following the blending of the aqueous formulation slurry for 5 minutes, the pH is adjusted to 7.1 to 7.2 with 20% potassium hydroxide. Then 710 lbs of high oleic safflower oil, preheated to 93 °C are added to the aqueous formulation slurry. Vitamin E acetate in the amount of 1.0 lbs and lecithin in the amount of 20 lbs are dissolved in 50 lbs of safflower oil and added to the aqueous formulation slurry. The mixture is then agitated to further the

emulsification and blending process for about 15 minutes. Maltodextrin in the amount of 1,550 lbs is then added. Butter flavor (6.7 lbs), and a vitamin dry mixture of 2.5 lbs of vitamin premix and 2.8 lbs of sodium ascorbate are added to the emulsified slurry. The emulsified slurry is then blended for 5 minutes and the total solids are adjusted to 38.5 % of the total weight of the emulsified slurry.

The emulsified slurry is then passed through a Moyno type pump exerting a hydroshear between 195 to 205 psi at 150 gallons per minute and then cooled to about 22 °C. The cooled slurry is then flavored with 23 lbs of vanilla flavoring to form the final supplement mixture. The cooled supplement mixture is then refrigerated at 2-4 °C and allowed to stand overnight before being subjected to UHT sterilization and aseptically packaged.

Comparative Macro- and Mineral Micro-Nutrient Values*

Composition	Example A		TRAUMACAL		PULMOCARE	
	Amount	% Daily Value**	Amount	% Daily Value**	Amount	% Daily Value**
Calories	200	***	178	***	178	***
Protein	10 g	20	9.8 g	19.5	7.4 g	17
Fat	13 g	20	8.1 g	12.5	11.05 g	4
Carbohydrate	11 g	4	17.0 g	5.5	12.5 g	4
Sodium	65 mg	3	140 mg	6.0	155 mg	6.5
Potassium	380 mg	10	165 mg	4.5	205 mg	6
Calcium	206 mg	20	88.5 mg	9.0	125 mg	12.5
Magnesium	82 mg	20	23.5 mg	6.0	50 mg	12.5
Phosphorus	210 mg	20	88.5 mg	9.0	125 mg	12.5
Iron	4.4 mg	20	1.05 mg	6.0	2.25 mg	12.5
Copper	0.42 mg	20	0.175 mg	9.0	0.25 mg	12.5
Zinc	3.2 mg	20	1.75 mg	12	2.8 mg	18
Iodine	33.0 mcg	20	8.85 mcg	6.0	18.75 mcg	12.5

* The values for 4 fluid ounces of TRAUMACAL and PULMOCARE are calculated based on the label information given for 8 fluid ounces (236 ml) of those prior art supplements.

** Percent Daily Values are based on a 2,000 calorie diet.

*** The U.S. Food and Drug Administration has not established % Daily Value.

Thus, an improved liquid nutritional supplement having improved flavor profile and taste which provides improved concentration of many recommended macro- and micro-nutrients in a shelf-stable form has been provided. One skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which are presented here for purposes of illustration and not of limitation, and that the present invention is limited only by the claims that follow.

WHAT IS CLAIMED:

1. A liquid nutritional supplement comprising:

(a) a macro-nutrient component comprising 22 to 150 milligrams of protein and 30 to 200 milligrams of fat per milliliter of supplement; and

(b) a mineral micro-nutrient component comprising 1.5 to 10 milligrams of potassium; 0.4 to 2.97 milligrams of calcium; 0.17 to 1.18 milligrams of magnesium; 0.42 to 2.97 milligrams of phosphorus; and 0.015 to 0.053 milligrams of iron per milliliter of supplement;

wherein the nutritional supplement is commercially sterile and shelf-stable.

2. The liquid nutritional supplement of claim 1, wherein the macro-nutrient component further comprises 50 to 350 milligrams of carbohydrate and the total solids present in the supplement is not less than 30% of the total weight of the supplement.

3. The liquid nutritional supplement of claim 2, wherein:

(a) the macro-nutrient component comprises about 85 milligrams of protein, about 110 milligrams of fat, and about 93 milligrams of carbohydrate per milliliter of supplement; and

(b) the mineral micro-nutrient component comprises about 3.2 milligrams of potassium; about 1.75 milligrams of calcium; about 0.69 milligrams of magnesium; about 1.78 milligrams of phosphorus; and about 0.037 milligrams of iron per milliliter of supplement.

4. The liquid nutritional supplement of claim 2, wherein:

(a) the macro-nutrient component comprises about 51 milligrams of protein, about 93 milligrams of fat, and about 237 milligrams of carbohydrate per milliliter of supplement; and

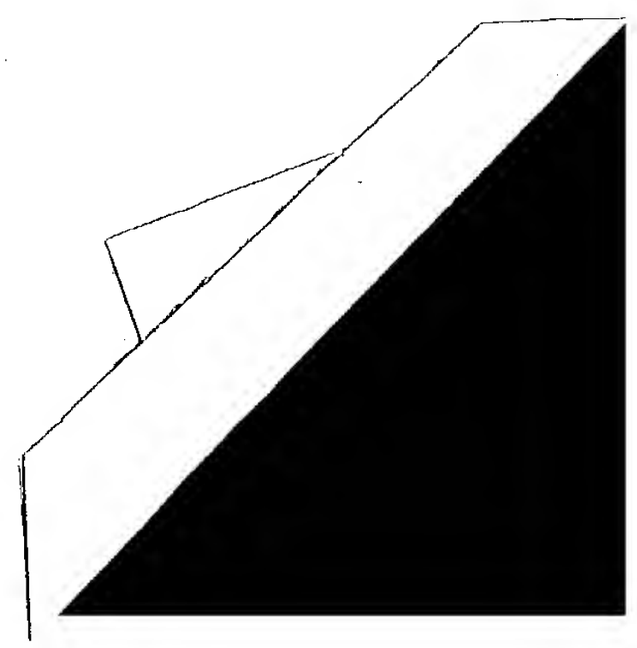
(b) the mineral micro-nutrient component comprises about 3.2 milligrams of potassium; about 1.75 milligrams of calcium; about 0.34 milligrams of magnesium; about 0.89 milligrams of phosphorus; and about .0195 milligrams of iron per milliliter of supplement.

5. A commercially sterile and shelf-stable liquid nutritional supplement comprising

(a) a macro-nutrient component comprising at least one source of protein, at least one source of fat, and at least one source of carbohydrate,

(b) a mineral micro-nutrient component comprising at least one source of mineral micro-nutrients which is virtually water-insoluble, and

(c) a stabilizer,



wherein the total solids present in the supplement is not less than 30% of the total weight of the supplement.

6. The liquid nutritional supplement of claim 5, wherein the virtually water-insoluble source of mineral micro-nutrients is selected from the group consisting of magnesium carbonate, ferric ortho-phosphate, and calcium carbonate.

7. The liquid nutritional supplement of claim 5, wherein the supplement is sterilized at least in part by continuous thermal processing at a temperature of at least 130 °C for a time sufficient to commercially sterilize the supplement.

8. The liquid nutritional supplement of claim 5 wherein a source of protein is calcium sodium caseinates.

9. The liquid nutritional supplement of claim 5 wherein a source of protein is milk protein concentrate which has been subjected to ultrafiltration to reduce lactose.

10. The liquid nutritional supplement of claim 5 wherein a source of fat is high in monounsaturated fatty acids.

11. The liquid nutritional supplement of claim 10 wherein a source of fat is high oleic safflower oil.

12. The liquid nutritional supplement of claim 5 wherein the source of carbohydrate is fine sugar, and the pH is adjusted to about 6.9 to 7.0.

13. The liquid nutritional supplement of claim 5 wherein a source of carbohydrate is fine sugar, an additional source of carbohydrate is maltodextrin, the pH is adjusted to about 7.0 to 7.2, and the total solids are not less than 38% of the total weight of the supplement.

14. The liquid nutritional supplement of claim 5 wherein the stabilizer is kappa-carrageenan.

15. The liquid nutritional supplement of claim 5 further comprising a wetting agent.

16. The liquid nutritional supplement of claim 15 wherein the wetting agent is selected from the group consisting of polysorbate 60 and polysorbate 80.

17. The liquid nutritional supplement of claim 5 wherein the mineral micro-nutrient component comprises sources of potassium, calcium, magnesium, phosphorous and iron.

18. The liquid nutritional supplement of claim 17, wherein the mineral micro-nutrient sources are selected from the group consisting of dipotassium phosphate, potassium

citrate, magnesium chloride, magnesium carbonate, calcium phosphate (tribasic) and calcium carbonate.

19. The liquid nutritional supplement of claim 5 further comprising a trace mineral micro-nutrient component comprising at least one source of iron, zinc, copper and iodine.

20. The liquid nutritional supplement of claim 19 wherein the sources of trace mineral micro-nutrients are ferric ortho-phosphate, zinc sulfate, copper gluconate, and potassium iodide.

21. The liquid nutritional supplement of claim 5 further comprising lecithin, vitamin E acetate, flavorings, vitamins and sodium ascorbate.

22. The liquid nutritional supplement of claim 5 wherein the supplement provides at least about 1.7 calories per milliliter.

23. The liquid nutritional supplement of claim 13 wherein the supplement provides at least about 2.0 calories per milliliter.

24. A liquid nutritional supplement sterilized by continuous thermal processing at ultra-high temperature comprising as a source of iron ferric ortho-phosphate.

25. A process for maintaining emulsion stability and extending the shelf life of a liquid nutritional supplement formulated as an emulsified slurry comprising sources of macro-nutrients and then sterilized, comprising the step of passing the emulsified slurry through a pump exerting a hydroshear of between 100 to 250 pounds per square inch.

26. The process of claim 25, further comprising the steps of

(a) cooling the supplement to a temperature below about 7 °C and

(b) allowing the supplement to stand for not less than 6 hours before sterilizing the supplement.

27. The process of claim 25 wherein the pump is exerting a hydroshear of between 195 to 205 pounds per square inch.

28. A process for aseptically sterilizing and homogenizing a liquid nutritional supplement comprising the steps of:

(a) heating the supplement to a temperature of at least 130 °C for a time sufficient to commercially sterilize the supplement while the supplement is passing through a hold tube under a pressure sufficient to keep the flow of the supplement through the hold tube substantially turbulent;

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(b) passing the supplement through a remote aseptic homogenizer having at least one valve creating a pressure of at least 2,800 pounds per square inch wherein the valve also acts as a pressure restrictor on the supplement flow out of the hold tube.

29. The process of claim 28, wherein the supplement is heated indirectly while flowing through a spiral hold tube.

30. The process of claim 29, wherein the supplement mixture is heated to a temperature of about 140 - 145 °C for about 2 to 45 seconds.

31. The process of claim 30, wherein the supplement mixture is heated to a temperature of about 142 - 144 °C for about 3 to 6 seconds.

32. The process of claim 28, wherein the supplement is passed through a second remote aseptic homogenizing valve creating a pressure of at least about 500 pounds per square inch.

33. The process of claim 32, wherein the supplement is passed through a double stage homogenizer having a first stage valve creating a pressure of 3,100 pounds per square inch and a second stage valve pressure creating a pressure of 500 pounds per square inch.

34. In a processor for commercially sterilizing a liquid having an entry point and an exit point for the liquid, a hold tube between the entry and exit points, a chamber holding steam adjacent the hold tube for indirectly heating the liquid in the hold tube to a temperature of at least 130 °C for a time sufficient to commercially sterilize the supplement while the supplement is passing through the hold tube, and a means for restricting the flow of the liquid out of the processor, the improvement which comprises:

(a) increasing the thickness of the walls of the hold tube so that the hold tube can withstand pressures up to 4,000 pounds per square inch;

(b) creating a continuous positive pressure through the system by the use of at least one positive displacement pump controlled by a variable speed drive; and

(c) dynamically controlling the pump, the processor, and the means for restricting the flow of the liquid out of the processor to ensure that the pressure remains sufficiently high to keep the flow of the liquid through the hold tube substantially turbulent.

35. The processor of claim 34, wherein the flow level of the liquid through the processor is between 2,000 and 8,000 liters per hour.

36. The processor of claim 34, wherein difference in pressure on the liquid at the entry point and the exit point is not more than 500 pounds per square inch.

37. The processor of claim 34, wherein the pressure within the hold tube is not less than 2,800 pounds per square inch.

38. In a processor for commercially sterilizing a liquid having a hold tube between the entry and exit points, and a chamber holding steam adjacent the hold tube for indirectly heating the liquid in the hold tube to a temperature of at least 130 °C for a time sufficient to commercially sterilize the supplement while the supplement is passing through the hold tube, the improvement which comprises:

maintaining a pressure on the liquid through the hold tube which is higher than the pressure on the steam in the chamber adjacent the hold tube, such that if a leak in the hold tube develops no steam will enter the hold tube and contaminate the liquid in the hold tube.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21303

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :Please See Extra Sheet.
US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/2, 8, 905; 426/72, 74, 590, 601, 656, 658; 366/136, 159, 160.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, STN MEDICINE CLUSTER

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- Y	US 5,108,767 A (MULCHANDANI et al) 28 April 1992, Cols. 5-6. 1, 3-4, 9-10, 12-14, 19	1-2, 5-7, 9-13, 17, 19, 21-23, 28, 32 --------- 3-4, 8, 18, 24
X --- Y	US 5,340,603 A (NEYLAN et al) 23 August 1994, Cols. 9, 20-22. 1-6, 12-13	5-7, 10-11, 17, 19, 21 --------- 1-4, 14, 18, 20, 24

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
05 FEBRUARY 1998	26 FEB 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JENNIFER HARLE Telephone No. (703) 308-0196

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21303

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- Y	US 5,545,411 A (CHANCELLOR) 13 August 1996, Cols. 1-6.	1-2, 5, 8-14, 17-19, 28, 32-33 ---------- 3-4, 18, 25, 27
X ---- Y	US 5,472,952 A (SMIDT, et al) 05 December 1995, Cols. 8-9.	1-2, 5, 10-11, 17, 19 ---------- 3-4, 6, 8, 18, 20
X ---- Y	US 5,520,948 A (KVAMME) 28 May 1996, Cols. 1-4. 8-9, 11-12	5, 8, 10-11, 17, 19 ---------- 28, 32
Y	US 4,419,369 A (NICHOLS et al) 06 December 1983, Col. 3, lines 16-18.	8
Y	GB-1135552 A (PFIZER & CO INC) 31 August 1993, Abstract.	6, 20, 24
A	US 4,591,463 (NAHRA, et al) 27 May 1986, Entire Document	34-38
A	US 4,844,620 A (LISSANT, et al) 04 July 1989, Entire Document	34-38
A	US 5,378,488 A (DIMLER et al) 03 January 1995, Cols. 1-4.	34-38
A,P	US 5,656,317 A (SMITS et al) 12 August 1997, Entire Document	34-38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21303

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest
☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21303

A. CLASSIFICATION OF SUBJECT MATTER:
IPC (6):

A01N 37/18; A61K 38/00, 38/16; A23D 7/00, 9/00; A23G 3/00; A23J 1/00; A23L 1/30, 2/00; A23K 1/175; B01F 15/02; G05D 11/00

A. CLASSIFICATION OF SUBJECT MATTER:
US CL :

514/2, 8, 905; 426/72, 74, 590, 601, 656, 658; 366/136, 159, 160.2

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group
I, claim(s)1-24, drawn to a liquid nutritional supplement.
Group II, claim(s) 26-33, drawn to a process form maintaining emulsion stability and extending shelf life.
Group III, claim(s) 34-38, drawn to an improvement in a processor for commercially sterilizing a liquid.

The inventions listed as Groups I, II, and III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the composition is its own distinct invention and the special technical feature of the composition is not required by Groups II and III. Additionally, the claimed apparatus, Group III is not specially adapted for the process of Group II.

The base claim of group II mentions a liquid nutritional supplement but it does not have to be the same liquid nutritional supplement claimed. This emulsification process could be applied to nutritional supplements other than those claimed by applicants, infant formula, dairy products and non-dairy creamers.

The apparatus of Group III does not have to be used in the process of Group II. Group II specifically deals with nutritional supplements while Group III is any liquid.